

Blister pack  
C1

17. The use of a mono- or multilayer film as claimed in claim 9 as backing film for blister packs.

18. The use of a blister pack as claimed in claim 17 for storing and transporting pharmaceutical products.

19. The use of a blister pack as claimed in claim 17 for storing and transporting dry oral pharmaceutical preparations. - -.

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**REMARKS**

Pursuant to the provisions of 37 CFR § 1.136 (a), applicants hereby petition the Assistant Commissioner to extend the time period to respond to the outstanding Office Action dated November 4, 1998, for three months, i.e. from February 4, 1999 up to and including May 4, 1999. A check for \$ 870.00 is included to cover the cost for this petition fee. Please charge any additional fees or credit any overpayments to deposit account 50-0320.

The present invention provides a mono- or multilayer film, which is useful for the backing film in a blister pack, which film is easy to process, has good barrier properties, especially with respect toward water vapor, is easy to recycle and which permits easy handling by the processor and final user.

The invention provides a mono- or multilayer film which comprises at least one layer of cycloolefin polymer. The mono- or multilayer film has, at a relative humidity of approximately 85% and a temperature of approximately 23°C, a water vapor permeation of  $\leq$  or 0.035g\*mm/m<sup>2</sup>d, a puncture resistance of  $\leq$  300N/mm, and a thickness of  $\leq$  100  $\mu$ m.

Claims 1-8 have been rejected under 35 USC § 112, first paragraph. Specifically claim 1 has been criticized with respect to the recitation of the "mixture of cycloolefin polymers with one or more thermoplastics".

Claims 1, 2 and 4 are also rejected under 35 USC § 102 (b) as anticipated by Breckner et al., U.S. Patent Number 5,422,397. It is maintained in the Action that all the elements of the claimed invention are either recited or inherent in Breckner.

Applicants submit that both these rejections under 35 USC § 102 (b), are unwarranted and should be withdrawn.

The Yamamoto patent describes a blister package having moisture-proofness and a film layer within such blister package containing a cycloolefin copolymer. However, Yamamoto fails to teach or suggest the orientation of such film. Applicants submit however, that orientation is an essential feature of the invention, since the non-oriented film, (see Example 1) is brittle and fractures easily (see page 13, line 5, of the specification as filed).

Breckner is concerned with polymer alloys comprising cycloolefin polymer and the use of such alloys for the preparation of moldings. However, Breckner fails to teach or suggest the orientation of films from cycloolefin polymers and the particular advantages of the mechanical properties resulting therefrom.

In view of the instant amendment, particularly, new claim 9 as presented herein, applicants submit that these rejections are rendered moot. New main claim 9 now contains the features originally present in claims 1 and 2, and further comprises the orientation feature formerly recited in claim 5. Applicants therefore urge that neither of the cited references anticipate the applicants' claimed invention.

Anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference. *In re Spada*, 15 USPQ2d 1655 (Fed. Cir. 1990). To constitute anticipation, all material elements of a claim. *Constant v. Advanced Micro-Devices, Inc.*, 7USPQ2d 1057 (Fed. Cir. 1988); *Richardson v Suzuki Motor Co.*, 9 USPQ2d (1989). For anticipation, there must be no difference between the claimed invention and the reference

disclosure. *Scripps Clinic & Res. Found V. Genetech, Inc.*, 18 USPQ2d 1001 (Fed Cir. 1988).

Exact identity is required.

Applicant respectfully contend that Yamamoto and Brekner both fail to teach each and every element of the claimed invention and therefore are not anticipatory references.

Applicants urge therefore that the rejections under 35 USC §102 (b) are overcome and should be withdrawn.

Claims 1-4, 7 and 8 are rejected under 35 USC § 103 (a), as unpatentable over Yamamoto. It is maintained in the Action that it would have been obvious to one of ordinary skill in the art at the time the invention was made, to replace the cycloolefin monomers of Yamamoto with homologues, given the reasonable expectation of “equivalent results and absent a showing otherwise”. (see Office Action at page 7, paragraph 5).

In response, Applicants maintain that the rejection of claim 1-4, 7 and 8 under 35 USC § 103 (a) as unpatentable over Yamamoto et al., is unwarranted and should be withdrawn. There is no hint or suggestion in Yamamoto with respect to the orientation of the film. Moreover, there is no recognition of the superior results obtained thereby.

Claims 5 and 6 are rejected under 35 USC § 103 (a), as unpatentable over Yamamoto in view of Tanaka, U. S. Patent Number 5,556,929. It is maintained in the Action that Tanaka discloses a monoaxially polypropylene film composition and it is further stated that it would have been obvious to one of ordinary skill in the art to have fabricated polymeric films that contain filler and are monoaxially stretched, since Tanaka suggests that such stretching and addition of anti-blocking agents leads to films of improved transparency and formability.

In response, applicants point out that the monocycloolefin polymer described by Tanaka is not in any way comparable with the cycloolefin copolymer employed by the

applicants' invention. Applicants urge that this rejection under 35 USC § 103 (a) is likewise unwarranted.

The Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art. *In re Piasecki*, 223 USPQ 785, 787-88 (Fed. Cir. 1984). The Examiner can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill **would have led** that individual to modify the relevant teaching of the references. *Ex parte Obukowicz*, 27 USPQ 2d 1063 (Bd. App. 1993).

The mere fact that certain reference could have been modified to arrive at the claimed combination does not make such a modification obvious, unless the reference suggests the desirability of such a modification. *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984).

In the instant case, applicants urges that it is only with the benefit of impermissible hindsight that the arguments concerning the arguments concerning the § 103 rejection can be put forth. There is nothing in Yamamoto, either alone, or together with Tanaka, which suggests the desirability of the modification proposed by the Examiner. In order to render a claimed invention obvious, the prior art must provide some motivation or reason for a worker in that art to make the necessary changes in the references without the benefit of applicants' own specification. *Ex Parte Chicago Raw Hide Manufacturing Co.*, 223 U.S.P.Q. 351, 353, (Bd. App. 1984).

Moreover, it is submitted that one of skill in the art could not have predicted the surprising benefits provided by the instant invention, by using either reference cited, either alone or in any fair combination. Particularly, Tanaka uses monocycloolefin polymer which has a different chemical composition of that of the present invention (see new claim 9).

Moreover, the oriented film of the present invention provides improved mechanical properties as demonstrated by the Examples set forth in the specification as filed.

Applicants submit that the showing of record is more than sufficient to demonstrate the surprisingly superior results obtained by the instant invention. Applicants have submitted specific data – not mere argument or conclusory statements – indicating improved properties. *In re Soni*, 34 USPQ 2d 1684, 1687 (Fed. Cir. 1995).

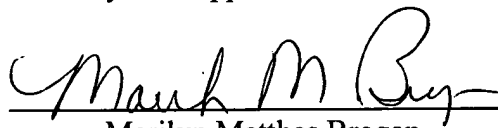
The oriented films according to the invention have an outstandingly high quality and are perfectly suitable to be used for blister packs, particularly for pharmaceuticals.

Applicants submit that the rejections under 35 USC § 103 (a) are unwarranted and should be withdrawn.

Applicants urge that the instant application is now in condition for allowance, the early notification of which is respectfully solicited.

Applicants take this opportunity to thank the Examiner for acknowledgement of their claim for priority under 35 USC § 119, and for acknowledgement of receipt of the certified copy of the priority documents, i.e. German Application 19644675.9 filed October 28, 1996, and German application 19725975.8 filed June 19, 1997.

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